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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,738	12/21/1999	JOSEPH J. CHANG	056301.P478	5325
7590 08/18/2004 WOOD, HERRON AND EVANS 2700 CAREW TOWER CINCINNATI, OH 45202			EXAMINER HAYES, MICHAEL J	
			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/469,738

Applicant(s)

CHANG, JOSEPH J.

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-32 is/are pending in the application.
- 4a) Of the above claim(s) 20-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 June 2004 has been entered.

### ***Election/Restrictions***

Newly submitted claims 20-32 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 20-32 are directed to a catheter unit including a needle secured to a housing and a flash chamber disposed at the proximal end of a housing found in class 604, subclass 168.01. Originally presented claims that have received an action on the merits (claims 14-19) are directed to a housing removably coupled to a tubular introducer sheath and a blunting member having an open proximal end adjacent a flash chamber, found in class 604, subclass 164.01

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Specification***

The amendments filed 07 October 2002 and 10 June 2004 are objected to under 35 U.S.C. 132 because they introduce new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

the amendment to the specification, received 7 October 2002, describing the relationship of hub rim 39 to the portion 77 of the securing member 75 is new matter not present in the application as originally filed.

the amendment received 01 June 2004 presents figs. 1, 2, 5a, 5b, and 6 that contain new matter not present in the application as originally filed. These figs appear to show a new embodiment that is a combination of originally filed figs. 1 and 4. The relationship of the seal between the securing member 75 and the flash chamber, as shown in fig. 4 is new matter. The relationship of a cutout on the chamber wall to hold the seal was not previously disclosed.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. New matter appears to be recited in claim 14 which recites a moveable member coupled to the blunting member and engaging an outer surface of the introducer sheath where the moveable member advances the blunting member when the sheath is removed. The advancing of the blunting member with such a moveable member was not previously described in the originally filed application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by SOLOMON et al. (US Patent No. 6,210,379). Solomon discloses a housing removably coupled to a sheath 26, a needle 24 extending therethrough, a blunting member 28 having a hollow lumen with a proximal end adjacent a flash chamber 30, a securing member 84 coupled to blunting member and engaging outer surface of sheath. See fig. 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over GOMEZ (EP 0 630 661) in view of SAHI (U. S. Patent No. 5,009,642) and CHANG (U. S. Patent No. EP 0 353 905). Gomez discloses a catheter unit including an introducer sheath 72, needle 76, and flash chamber 78 having a flash plug 80. Gomez does not disclose a hollow blunting member fitting within the needle bore, a porosity for the flash plug, or a moveable member coupled to a blunting member and engaging an outer surface of the introducer sheath for advancing the blunting member. Sahi teaches the use of a hollow blunting member to protect against needle injury and to communicate with a flash chamber where a moveable member 22 is coupled to the blunting member and engages the outer surface (i.e., surface of 42b) of the introducer sheath 40 (Figs. 2-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the blunting member and moveable member of Sahi in the device of Gomez in order to provide safe and accurate use of the medical device to prevent accidental injury due to the needle. Chang teaches the use of a UHMWPE flash plug with various porosities within the range of 35-55% (pg. 4, Table; claim 9) to provide for rapid filling of the flash chamber and thorough sterilization. It would have been obvious to one of ordinary skill in the art at the time

of the invention to use the porosities as taught by Chang in the catheter unit of Gomez and Sahi in order to provide a sterilizable device with efficient flash chamber.

### ***Response to Arguments***

Applicant argues that the securing member is shown engaging the outer surface of the sheath. The examiner has objected to this drawing and description in the specification as new matter, as discussed above.

Applicant argues that Sahi does not show a securing member coupled to the blunting member and engaging an outer surface of the introducer. The examiner maintains the rejection in view of the disclosure of Sahi that states “the connector 18 engages the retainer 32 to provide a lost motion connection between the blunting device 28 and the needle 12.” (Abstract). This statement in view of figs. 1 and 2 describe a securing member (generally at 18, more specifically portion 22, as seen in fig. 2) coupled to the blunting member (portion 32 of blunting member) and engaging an outer surface of the sheath (portion 42b as see in figs. 2 and 3).


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
16 August 2004



**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**